

Pursuant to rule 121(c)(3), the version of the amended claims to show changes made is submitted in a separate paper enclosed herein.

#### SUMMARY OF AMENDMENTS

Claims 1, 5, 8 and 17 (and all other remaining claims by virtue of dependency) have been amended to recite the limitation that binary end of the rod maintains contact with the fluid flow in all positions. Support for these amendments can be found at page 9, lines 2-4. Pursuant to rule 121(c)(3), the version of the amended claims to show changes made is submitted in a separate paper enclosed herein.

#### REMARKS

##### 35 USC 112 first and second paragraph

The Examiner has rejected claims 1-5 and 8-17 for failing to recite the limitation that the rod always be in contact with the fluid under 35 USC 112, first and second paragraph. With respect to this point, the Applicant takes issue with the Examiner's view of the requirements of 35 USC 112 and In re Mayhew. However, the Applicant recognizes that whatever the Applicant's view of the law, the limitation complained of by the Examiner is nevertheless inherent in the operation of the Applicant's invention. Accordingly, the Applicant has amended dependent claims 1,5,8, and 17 to recite this limitation, and therefore respectfully requests that the Examiner remove the Examiner's rejection on this basis.

##### 35 USC 103(a)

The Examiner has rejected claims 1-17 over the Applicant's admitted prior art in view of Johncox et al (U.S. Patent No. 4,750,707) and Krambrock (U.S. Patent No. 4,836,250). The Examiner has argued that it would have been obvious for one of ordinary skill in the art to replace the admittedly known movable valve member of the system described in Applicant's figs 4a and 4b with either of the valves shown in Johncox or Krambrock stating "this reference valve member is capable of controlling material flow through a column chamber in substantially the same manner as the valve member of the admittedly known

system to produce substantially the same results." This statement is simply false.

Since both the Johncox and Krambrock valves do not allow the flow of a fluid in all positions, a limitation specifically required in the claims, they could NOT simply be substituted for the movable valve member of the system described in Applicant's figs 4a and 4b to "produce substantially the same results." Indeed, to "produce substantially the same results" they would need to be operated in a manner consistent with the system described and claimed by the applicant. As such, they would have to be modified to allow the flow of a fluid in all positions. The Examiner concedes that the suggestion that they be so modified is nowhere to be found in either Johncox or Krambrock.

Recognizing that a proper prima facie case of obviousness cannot be formed absent a reference teaching or suggestion the required modification, the Examiner then simply proposes the modification of his own volition. The Examiner asserts that such is simply inherent in the mere existence of the admitted prior art. However, such a suggestion is entirely improper. Quoting from the MPEP "[w]hen an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory *must be provided*. In re Grose, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979) see In re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420-421 (CCPA 1970) Plainly, no such evidentiary support is possible, as the Examiner is exclusively on the Applicant's disclosure to suppose the prior art makes such a suggestion. No such support is possible as the application itself is a claim that this very modification is novel and unobvious. Still quoting the MPEP, ("[A]ssertions of technical facts in areas of esoteric technology *must always be supported by citation of some reference work*" and "allegations concerning specific 'knowledge' of the prior art, which might be peculiar to a particular art *should also be supported*." In relying on the Applicant's disclosure for knowledge of the reference work, the Examiner fails to meet this burden. Finally, the MPEP provides: "the applicant must be given the

opportunity to challenge the correctness of such assertions and allegations. "The facts so noticed serve to 'fill the gaps' which might exist in the evidentiary showing" and *should not comprise the principle evidence upon which a rejection is based.*)" (italics added). The Examiner has thus done that which is specifically forbidden by the MPEP; the Examiner has used as the principle grounds for rejection the Examiner's suggestion that the device be modified in the precise manner taught by the Applicant. This is classic hindsight reconstruction, and is plainly unallowable. "It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch*, 972 F. 2d 1260 , 223 USPQ 2d 1780, 1784 (Fed. Cir. 1992) (quoting *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988)).

In any event, concurrent with this amendment, the Applicant has now placed into evidence the affidavit of Brian Dockendorff, a skilled artisan familiar with both the prior art system described in the Applicant's specification, and the system claimed by the Applicant. The Examiner's unsupported conjecture concerning the penultimate determinations upon which the question of obviousness turns are flatly contradicted by this evidence. In a nutshell, Mr. Dockendorff makes plain that not only was the use of the leaky binary rod claimed by the Applicant not obvious to those having skill in the art, but also that this development addressed a long felt need related to the drawbacks and disadvantages of the exact prior art the Examiner wishes to rely upon to establish obviousness.

The Applicant therefore respectfully requests that the Examiner withdraw the objections.

Closure

Applicant has made an earnest attempt to place the above-referenced application in condition for allowance and action toward that end is respectfully requested. Should the Examiner have any further observations or comments, he is invited to contact the undersigned for resolution.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Homan, et al.	) Art Unit: 1724
Serial No: 09/177,902	) Examiner: Ivars C. Cintins
Filed: 10/23/98	) Paper No: 12
For: METHOD AND APPARATUS FOR PACKED COLUMN SEPARATIONS AND PURIFICATIONS	) File No: E-1658
	) Date: January 22, 2002

Version of Amended Claims to Show Changes Made

Claims 1, 5, 8, and 17 were amended as follows where underlined matter was inserted and bracketed matter deleted:

1. (twice amended) A method of packing and unpacking a column chamber, comprising the steps of:  
flowing a mixture of a matrix material and fluid into a column chamber and forming a packed column from the matrix material, said column chamber having a first port for receiving said mixture, and outlet port and an actuator port wherein said actuator port is provided as having a rod having a binary end placed within said actuator port wherein said binary end of said rod blocks the flow of said matrix material to said outlet port in a first position, permits the flow of said matrix material to said outlet port in a second position, and maintains contact with said fluid flow and allows the flow of said fluid through said outlet port in all positions;  
capturing said matrix material and permitting said fluid to flow therepast by positioning said binary end of said rod in said first position; and  
opening said outlet by positioning said binary end of said rod in said second position, thereby permitting said matrix material and said fluid to

flow through said outlet port thereby unpacking the matrix material from the column chamber.

5. (thrice amended) A method of forming a packed column comprising:  
providing a column chamber, the column chamber having an inlet end and an outlet end, the outlet end having an actuator port and a flow port, the flow port alternately open or partially obstructed by a binary end of a rod placed in the actuator port wherein said binary end of said rod blocks the flow of a matrix material in a first position, permits the flow of said matrix material in a second position, and maintains contact with said fluid flow and allows the flow of a fluid in all positions; and  
flowing a mixture of a first fluid and a matrix material into the column chamber through the inlet end for packing the matrix material within the column chamber.

8. (twice amended) A method for purifying a component of a sample comprising:  
providing a column chamber, the column chamber having an inlet end and an outlet end, the outlet end having an actuator port and a flow port, the flow port alternately open or partially obstructed about a binary end of a rod placed in the actuator port wherein said binary end of said rod blocks the flow of a matrix material in a first position, permits the flow of said matrix material in a second position, and maintains contact with said fluid flow and allows the flow of a fluid in all positions;  
flowing a first fluid and a matrix material into the column chamber through the inlet end and along a first flow path to form a packed column of the matrix material within the column chamber, the rod holding the matrix material and permitting flow of the first fluid therethrough, the matrix material being configured to selectively retain a component of the sample;  
flowing the sample through the packed column for separating the component from the rest of the sample;

unobstructing the flow port; and  
flowing a second fluid through the column to remove the matrix material  
from the column chamber.

17. (twice amended) A method for purifying a biological sample comprising:  
providing a column chamber, the column chamber having an inlet end and  
an outlet end, the outlet end having an actuator port and a flow port, the  
flow port partially obstructed with a rod with a binary end wherein said  
binary end of said rod blocks the flow of a matrix material in a first  
position, permits the flow of said matrix material in a second position, and  
maintains contact with said fluid flow and allows the flow of a fluid in all  
positions;  
flowing a mixture of a first fluid and a matrix material into the column  
chamber to form a packed column of the matrix material within the column  
chamber, the matrix material being configured to selectively retain a  
biological sample; flowing a sample containing the biological sample  
through the packed column to separate the biological sample from other  
components of the sample; flowing a second fluid through the column  
chamber to remove the matrix material from the column chamber.